REMARKS/ARGUMENTS

Claims 38 to 52, 54 to 58, and 60 to 72 are in the application. Claims 1, 53, 59, has been cancelled. Claims 38, and 60 have been amended. Claims 69 to 72 have been added. No new matter is believed added. Claim 53 has been cancelled because it is redundant in view of the amendments made to claim 38. Claim 59 has been cancelled because it is inconsistent with the amended version of its parent claim, claim 38. Claim 60 has been amended for consistency with claim 38. A Supplemental Information Disclosure Statement and PTOL 1449 form accompany this response.

Rejection under 35 USC §112

Claim 68 is rejected under 35 USC §112, first paragraph as failing to comp0ly with the enablement requirement. Applicants respectfully traverse this rejection and request reconsideration.

Claim 68 has been reviewed and is believed to define accurately the process depicted in FIG. 7 and described at page 29, lines 2-25, and to be fully supported by that description and drawing. The claim closely tracks the steps described on page 29.

The only support offered for the Examiner's conclusion that claim 68 is not enabled is the observation that it appears from claim 68 that the finished products obtained are two separate capsule compartments. The applicant's finished product is an integrated dosage form having at least two capsule compartments that are separate in the sense that they are spaced from each other, but not separate in the sense that they are relatively movable. Claim 68 recites the step of inserting a first plug portion of a linker into an open end of one capsule compartment, and the step of inserting the other plug portion of the linker into the open end of the other capsule component. By the language of the claim, both plug portions are plug portions of the same linker. Therefore, the finished product is necessarily an integrated dosage form having two capsule compartments that are separate in the sense that they are spaced from each

other, but not separate in the sense that they are relatively movable. In other words, the product is an integrated dosage form, and the specification provides a full description of the process for producing the integrated dosage form.

In view of these remarks, withdrawal of the rejection to Claim 68 is respectfully requested.

Rejection under 35 USC §102(b)

Claims 1, 38, 39, 51-56, 58, 59, and 61 to 68 are rejected under 35 USC §102(b) as being anticipated by Goodhart et al. (US Patent No. 5,074,426). Applicants respectfully traverse this rejection.

Claims 1, 38, 42 to 44, 58, and 61 to 68 are rejected under 35 USC §102(b) as being anticipated by Graham (US Patent No. 5,085,033). Applicants respectfully traverse this rejection.

Both of these rejections will be addressed by Applicants together in the remarks below.

In each of the embodiments depicted in Applicants specification, in FIGs. 1-6A, the sub-units are joined by the mating of plugs and sockets, and secured together by welds. For example, in FIG. 1, a plug 13A, which is an integral part of a sub-unit 13, fits into a socket formed by the mouth of sub-unit 14, a plug formed as a unitary part of sub-unit 12 fits into a socket formed in sub-unit 13, and a plug formed as a unitary part of the cap 15 fits into a socket formed by the mouth of sub-unit 12. The sub-units are disposed in a line, and the plugs and sockets are radially smaller than the sub-units. The elements are secured together by welds at the joints. The other figures show similar plug-and socket joints in other variations of the dosage form.

Claim 38 has been amended to define the above-described plug and socket structure.

By virtue of the amendment to claim 38, the claim now defines a structure comprising at least two sub-units, in which at least two of the sub-units are drug substance-containing sub-units, in which at least two of the sub-units are joined by a joint comprising a plug and a socket, the plug and socket being unitary parts of, and radially smaller than, their respective sub-units, and in which the joined sub-units are welded together. New dependent claim 69 requires all of the sub-units to be joined by a joint as defined in claim 38.

The dosage form, as claimed in claim 38, is not suggested in the prior art. Goodhart describes various multi-part capsules, including capsules having joints composed of reduced plugs and sockets in FIGs. 13-26, but these joints are expressly described as enabling easy separation of the components of a dividable capsule by a pulling, bending or twisting motion (column 5, lines 56-62). Securing the elements by a weld would be contrary to Goodhart's expressed objective. The remaining references do not supply any suggestion to weld the reduced plug and socket joints of Goodhart's FIGs. 13-26.

Graham only discloses conventional telescoping capsule shells, with no disclosure or suggestion of the presently claimed construction. In Graham, there is also no disclosure of the specific joint structure defined in claim 38. Moreover, new dependent claim 70 recites that the drug substances in at least two of the sub-units are different. In contrast, in Graham, the capsule ingredients are apparently the same in both halves of the capsule.

Therefore, in view of these remarks and amendments, reconsideration and withdrawal of the rejection to the claims under 35 USC §102 is respectfully requested.

Rejection under 35 USC §103

Claims 1, 38 to 41, 51 to 59, and 61 to 68 are rejected under 35 USC §103 (a) as being unpatentable over Goodhart et al. (US Patent No. 5,074,426) in view of

Sivaramakrishnan et al. (WO 90/11070). Applicants respectfully traverse this rejection.

Claims 1 and 38 to 68 are rejected under 35 USC §103 (a) as being unpatentable over Goodhart et al. (US Patent No. 5,074,426) in view of Amidon et al. (US 5,674,530). Applicants also respectfully traverse this rejection.

Both of these rejections will be addressed by Applicants together in the remarks below. Applicants incorporate their above noted remarks on Goodhart with respect to the rejection under 35 USC §103.

In addition to the above comments, and amendments to claim 38, dependent claims 54-57, 63 and 64 contain additional limitations that further distinguish the present invention from Goodhart. Since the intent of Goodhart is to provide divisible capsules, necessarily Goodhart has to make two independent closed capsule compartments, which are then connected in their closed state so they can be separated. Claims 54 - 57, 63 and 64 define a dosage form in which a sub-unit has a mouth or mouth opening, and in which the mouth or mouth opening cooperates with an "element," "plug," or "cap" to complete the enclosure of a drug substance in the sub-unit. Thus, the Goodhart structure can be taken apart, as intended, whereas the claimed structure cannot be taken apart without spilling the capsule contents.

Claims 63 and 64 are specifically directed to dosage forms in which two adjacent sub-units have mouth openings in which plugs of a linker unit fit, completing the enclosure of the drug substances in the sub-units. No suggestion of such a structure appears in the art of record. Nor is there a disclosure of the rim and abutment surface of claim 63 or the rim and shoulder of claim 64.

New claims 71 and 72, which are dependent on claim 63, are directed to the welds connecting the sub-units to the linker units. Claim 63 is directed to a dosage form of the kind shown in FIGs. 6A, 6B and 6C, which has a joint structure particularly

adapted to welding, especially ultrasonic welding.

Reconsideration of the rejection of Claim 67 is also requested. The claim defines a set of multi-component dosage forms in which a capsule compartment from one dosage form of the set is interchangeable with a solid matrix from another dosage form of the set. As pointed out in the specification, the interchangeability of parts facilitates rapid prototyping of a dosage form comprising a combination of different drug substances in respective sub-units, and/or combinations of the same or different drug substances with different release characteristics, while simplifying the formulation procedure. The cited art does not teach the interchangeability feature defined in claim 67.

Reconsideration of the rejection of claim 68 is also requested. The claimed steps, and particularly the steps of inserting plug portions of a linker into respective capsule compartments, is not taught in the art of record.

For the reasons set forth above, the Applicants' claims distinguish the invention from Goodhart in such a way that, even if the teachings of Sivaramakrishnan or Amidon were applied to Goodhart, the result would not correspond to the claims.

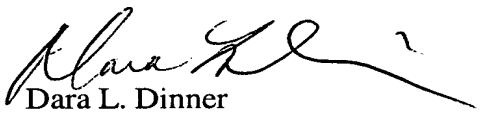
In addition, regarding the rejection on Goodhart in view of Sivaramakrishnan, Sivaramakrishnan discloses an utterly different type of capsule construction in which there is an inner rupturable capsule compartment completely surrounded by the outer compartment. This does not suggest the present claimed capsule structure, and points away from the present by teaching that the inner capsule compartment needs to be shielded by the outer compartment rather than being in end-to-end relationship therewith as set forth in claim 38. Sivaramakrishnan contains nothing that suggests the plug and socket structure of claim 38, in which each of the plug and socket is radially smaller than the sub-unit of which it is a unitary part. Nor does it suggest the interchangeable capsule and solid matrix structure of claim 67 or the multi-step process, utilizing a linker, as specifically defined claim 68.

Concerning the rejection on Goodhart in view of Amidon, Amidon likewise does not suggest a plug and socket structure in which each of the plug and socket is radially smaller than the sub-unit of which it is a unitary part. Nor does Amidon suggest the interchangeable capsule and solid matrix structure of claim 67 or the multi-step process, utilizing a linker, as specifically defined claim 68. Moreover, while Amidon describes a drug delivery system incorporating a plug, the plug, which fits into an end of a capsule part, the plug is not a unitary part of a sub-unit as defined in claim 38, i.e. a sub-unit selected from a linker, a closure cap, a drug substance-containing capsule compartment, etc.

For the above reasons, the Applicants respectfully submit that the invention, as set forth in claim 38 as currently amended, in its dependent claims, and in independent claims 67 and 68, is neither anticipated, nor shown to have been obvious, by the prior art, and request favorable reconsideration and the issuance of a notice of allowance.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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